PB89-108724

Pesticide Fact Sheet Number 174
Sodium Fluoracetate (Compound 1080)

(U.S.) Environmental Protection Agency
Washington, DC

Oct 88

U.S. Department of Commerce
National Technical Information Service
NTIS

50272-101

REPORT DOCUMENTATION PAGE	1. REPORT NO.	2.	3. PB89-108724

4. Title and Subtitle

EPA Pesticide Fact Sheets - Sodium Fluoroacetate (Compound 1080) No. 174

5. Report Date
October 1988

6.

7. Author(s)
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8. Performing Organization Rept. No.
540/FS-88- 126

9. Performing Organization Name and Address
U.S. Environmental Protection Agency
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Washington, D.C. 20460

10. Project/Task/Work Unit No.

11. Contract(C) or Grant(G) No.
(C)
(G)

12. Sponsoring Organization Name and Address
Same as #9

13. Type of Report & Period Covered

14.

15. Supplementary Notes

16. Abstract (Limit: 200 words)

This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the the following actions has occurred.

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

17. Document Analysis a. Descriptors

Pesticides, regulations, Chemical Information Fact Sheet, Use Patterns, science findings.

b. Identifiers/Open-Ended Terms

REPRODUCED BY
U.S. DEPARTMENT OF COMMERCE
NATIONAL TECHNICAL INFORMATION SERVICE
SPRINGFIELD, VA. 22161

c. COSATI Field/Group

18. Availability Statement:	19. Security Class (This Report)	21. No. of Pages
Publicly Available	Unclassified	6
	20. Security Class (This Page) Unclassified	22. Price

United States
Environmental Protection
Agency

Office of Pesticides and Toxic Substances
Office of Pesticide Programs (TS-766C)
Washington, DC 20460

540/FS-88-126

EPA

Pesticide Fact Sheet

Name of Chemical: SODIUM FLUOROACETATE (COMPOUND 1080)
Reason for Issuance: CANCELLATION/DENIAL/SUSPENSION/DATA CALL-IN
Date Issued: OCTOBER 1988
Fact Sheet Number: 174

1. DESCRIPTION OF CHEMICAL

Generic Name: Sodium Fluoroacetate
CH_2F-COON

Common Name: 1080

Trade and Other Names: Compound 1080, Sodium monofluoroacetate, Ratsbane

EPA Shaughnessy Code: 075003-4

Chemical Abstracts Service (CAS) Number: 62-74-8

Pesticide Type: Vertebrate Pesticide

U.S. Producers: Only one manufacturer, Tull Chemical Company, Inc., sells compound 1080 manufacturing use (technical) product in the United States.

2. USE PATTERNS AND FORMULATIONS:

The principle use of compound 1080 is to control field rodents. Thirty nine rodenticide end-use products are currently authorized for use: 35 with California counties, 2 with the Colorado Department of Agriculture, and 1 with Klamath County, Oregon. The California and Colorado products have intrastate registrations. Klamath County has a "special local need" registration.

Montana, Wyoming, Ranchers Supply of Alpine, Texas, and the U.S. Department of Agriculture currently have Federal Registrations for 1080 Toxic Collars. This use will be affected as the Agency will require data to support a registration for a 1080 technical product to be used only in formulation of livestock protection collars.

Formulation Type: Compound 1080 rodenticide is formulated into grain baits at 0.2% to 0.11%. The registration for 1080 water baits was cancelled in 1986.

3. AGENCY ACTION:

EPA is taking a number of regulatory actions involving 1080 registrations and applications for registrations, since data required to support the registration of 1080 rodenticide products has not been submitted in accordance with Agency requirements. The Agency is issuing:

1) A notice of intent to deny the registration of intrastate products (20 California counties; Colorado Department of Agriculture) for which a complete application for Federal registration was submitted prior to July 31, 1988, in accordance with 40 CFR 152.230.

2) A notice of intent to cancel the registration of the one technical grade compound 1080 product (Tull Chemical Co.).

3) A notice of intent to suspend the one end-use federally registered 1080 rodenticides (Klamath County, Oregon).

4) A data call-in notice [Federal Insecticide, Fungicide, and Rodenticide Act section 3(c)(2)(b)] requiring product chemistry data to support a technical grade compound 1080 product to be used only in livestock protection collars (USDA, Montana Department of Livestock, Wyoming Department of Agriculture, Ranchers Supply Co.).

No actions, other than requests for minimal product chemistry data, are being taken with respect to the 1080 livestock protection collar registrations.

4. BACKGROUND:

The principal use of compound 1080 is to control field rodents. It was available for this use in California, Colorado, Nevada, and Oregon because these states had valid "intrastate" registrations. Other states which had used 1080 for field rodent control relied on the U.S. Department of the Interior registration, which was withdrawn following a 1972 Executive Order prohibiting the use of compound 1080 on federal lands. Prior to 1972, 1080 was also used for predator control, principally coyotes.

California uses over 80 percent of the compound 1080 as a field rodenticide; the bulk is used to control ground squirrels. The only Federal Registration for field rodent use is a "Special Local Needs" registration granted to Klamath County, Oregon.

On July 31, 1985 the Agency concluded a Special Review on Sodium Fluoroacetate (1080) with the finding that: 1) use of compound 1080 to control field rodents may have adverse effects on nontarget wildlife; 2) these risks could be reduced by modifying the labeling of the products and, in certain cases, by reducing the concentration of compound 1080 in rodenticide baits. However, the Agency was unable to determine whether additional regulatory restrictions were needed due to the lack of critial data. Accordingly, the Agency conditioned any future use of the 1080 rodenticide on the immediate adoption of certain risk reduction measures and on the submission of the full complement of data required for Federal Registration.

The Agency's current action on compound 1080 registrations relates to the failure of registrants to satisfactorily respond to two DCI Notices. In November, 1985, a Notice Requiring Submission of Full Applications for Federal Registration for all intrastate products was sent to states with intrastate registrations (40 CFR 162.17). A DCI Notice was also issued to California, Colorado and Nevada requiring the submission of data to support compound 1080 Federal Registrations. Similar DCIs were also issued to Tull Chemical Co., Inc. and Klamath County. Tull Chemical Co. declined to submit data, but the California Department of Food and Agriculture (CDFA) agreed to provide the data for the company.

Prior to issuing the November 1985 DCI, the Agency met with registrants and interested user groups to explain, among other things, why data were required and how to generate the data.

Thirty six applications for Federal Registrations were submitted by CDFA, and two were submitted by the Colorado Department of Food and Agriculture. The Nevada Department of Agriculture failed to submit Federal Registration applications for its three intrastate products.

In December 1986, the Agency received data from CDFA and the Colorado Department of Agriculture to support the compound 1080 rodenticide use for California, Colorado, Klamath County, and for the technical 1080 registration for Tull Chemical Co., Inc. However, upon review of the data, the Agency determined that the submissions by California and Colorado are unsatisfactory for the following reasons:

1. Inadequate safety data to determine hazards to nontarget fish, birds, and mammals.

2. Lack of specific directions for 1080 use to enable the Agency to determine the food/feed sites for which coumpound 1080 is/has been used so applicable data requirements can be determined; and

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3. No validated analytical method with detection limits low enough to determine concentrations of compound 108Q at the level of concern.

A second public meeting was held in October 1987 where the Agency again explained why the data were required and clarified procedures for data development.

On December 15, 1987 another DCI Notice was issued to California, Colorado, Tull Chemical Co., Inc., and Klamath County. This Notice required the submission of four additional environmental fate studies.

On December 17, 1987 the compound 1080 registrants were notified that the Agency would extend the data due dates in the 1985 DCI Notice if the registrants submitted the following items within 30 days: 1) a commitment to fulfill the data requirements, 2) legible draft revised labels, with the use of sites clearly defined; and 3) A Confidential Statement of Formula (EPA Form 8570-4). In addition, progress reports were required for many long-term studies required by the DCI.

Additional data were submitted by CDFA in May 1988, to support compound 1080 use in California, Colorado, Klamath County, and the technical registration for Tull Chemical Co., Inc. Upon Agency review, the data were again found to be unsatisfactory. When CDFA also requested waivers of many of the data requirements, the Agency denied the request.

The Agency is taking action against all rodenticide compound 1080 registrations because of the lack of progress toward completing the DCI long-term data requirements, failure to submit the DCI short-term requirements by the due dates, unacceptable qualifications to the commitments to satisfy data requirements, and failure to submit administrative forms.

The Agency is requiring the four compound 1080 toxic collar registrants to register a compound 1080 manufacturing-use product (technical) to be used only in the formulation of livestock protection collars. The data required to support this registration will involve only product chemistry requirements.

The Agency also will be taking action with regard to the registrations of strychnine products, another vertebrate control pesticide. The Agency is issuing a rescissioin of the authority to sell or distribute intrastate products, and initiating a process to suspend the remaining strychnine registrations until all data required by three Data Call-In Notices are submitted to the Agency and, upon Agency review, are found to be acceptable. (These actions against strychnine are independent of the temporary cancellation action required by the April 11, 1988 order of the United States District Court for the District of Minnesota in the case of Defenders of Wildife v. Administrator.